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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,911	09/05/2003	Arturo J. Angel	524522000500	7674

25226 7590 06/06/2007
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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06/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/655,911	Applicant(s) ANGEL ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-44 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 14-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/16/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of REC, amendment and response dated 3-16-07 is acknowledged.

Claims 1 and 3-44 are pending. Elected claims 1, 3, 4 and 10-13 have been considered for examination. Non-elected claims 5-9 and 14-44 have been withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-16-07 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,910,512 to Conant (Conant) in view of Wholehealthmd (cited in action dated 6-15-03).

Instant claims are directed to a kit comprising separately packaged components, a first composition comprising capsaicin or its analog and a second component comprising a substance in which capsaicin has a solubility of at least 10%, wherein the

second composition cleansing the bodily surface by removing the capsaicin or capsaicin analog remaining on the skin after application of the composition.

Conant teaches a topical analgesic composition comprising capsicum and/or capsaicin, for the treatment of pain and relief from arthritis (col. 1-2). Conant suggests a water-soluble capsaicin at a concentration of 0.1 to 1% (col. 2), which false within the claimed percentage of capsaicin or its analogue of instant claims 11-13. Conant teaches water as an excellent for capsaicin and hence meets the claimed solubility suspending (at least 10% w/w). Conant teaches applying water-soluble capsaicin to the skin so that the epidermal layer is softened without harsh chemicals (col. 1, lines 57-60) and also teaches suspending the water-soluble capsaicin in hydrophilic bases before applying to the skin of patients to treat pain.

Conant fails to teach the claimed kit having separate components. Instant claims state components but fail to state what are the components separated and nor do specifically state that the first and second compositions are separated. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to pack capsaicin and the solvent or the carrier for capsaicin separately and mix them before applying to skin because Conant teaches suspending water soluble capsaicin in various hydrophilic bases before applying to the skin for treating pain and therefore a skilled artisan would have expected capsaicin to be soluble in water and is therefore effective in treating pain, before applying.

Wholehealthmd teaches a capsaicin product for relieving pain and arthritis. The reference suggests that capsaicin causes stinging and burning sensation, and suggests

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washing the hands thoroughly after applying the cream. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include a second component that cleanses the residual capsaicin after applying, in the teachings of Conant, because Wholehealthmd teaches that capsaicin causes burning and stinging and suggests diluting capsaicin. Further, it would have been obvious for a skilled artisan to separate the second (diluting composition) from the capsaicin composition because one would not achieve the pain relief effect when capsaicin is diluted by adding a diluent to the actual capsaicin composition. Thus, it would have been within the scope of a skilled artisan to prepare kit with capsaicin and a diluent that cleanses capsaicin.

Response to Arguments

Applicants' arguments filed on 3-16-07 have been considered but not found persuasive.

It is argued that Conant fails to set forth a prima facie obviousness because there is no teaching, suggestion and motivation to prepare a kit comprising two components- capsaicin or its analog and a cleansing because Conant is only directed to relieving pain and not its removal or elimination of pungent and contamination. It is argued that Conant does not teach removal of capsaicin. However, instant rejection is not over the teachings of Conant alone and instead Conant in view of Wholehealthmd, wherein the latter teachings suggest that when capsaicin is applied for the same purpose as that taught by Conant i.e., relieving pain, it causes burning and stinging and therefore should

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be removed by diluting capsaicin. Thus, the second reference provides the requisite motivation to incorporate a separate component that dilutes capsaicin to prevent burning sensation. During the telephonic interview dated 4-27-07, examiner informed the same to applicants' representative, Ms. Lisa Amii. The examiner informed that Wholehealthmd teaches washing capsaicin by dilution so as to remove capsaicin and prevent burning and stinging sensation.

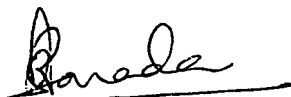
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
May 29, 2007

A handwritten signature in black ink, appearing to read 'Lakshmi S. Channavaajjala', written over a horizontal line.

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER